DEPARTMENT OF HEALTH HUMAN SERVICES

HFD-305

Food and Drug Administration
Rockville MD 20857

DEC 7 2004

Christina M. Markus, Esq.
King & Spalding LLP
1700 Pennsylvania Avenue, NW
Washington, DC 20006-4706

Re: Docket No. 2004P-0262/CP1

Dear Ms. Markus:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on June 10, 2004. Your petition requests that the Agency rescind a suitability petition decision regarding tablet and capsule analgesic products containing 325 mg acetaminophen, 50 mg butalbital, 40 mg caffeine, and 5 mg hydrocodone bitartrate (93P-0346/CP1) in light of the Pediatric Research Equity Act of 2003.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2004P-0262

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